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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

BNSF, Plaintiff vs. CARD, Defendant.	CV-19-40-M-DLC **CARD'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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I. Introduction

BNSF brought this qui tam action, alleging the Center for Asbestos Related Diseases (CARD) violated the False Claims Act, 31 USC §3729(a)(1)(A), for presenting false claims for payment to the federal government, (B) for false records and statements, and (G) for false records and statements material to an obligation to pay. After BNSF filed suit, the Office of Inspector General for the Department of Health and Human Services contacted CARD and requested CARD to provide extensive information about its patients and practices. After reviewing the information and conducting numerous interviews, the United States declined to prosecute BNSF's action against CARD. BNSF then proceeded to prosecute this case itself.

BNSF's suit, brought for whatever ulterior motives BNSF may have, is meritless. This Court must grant summary judgment to CARD.

II. Undisputed Facts

Libby was the site of a vermiculite mining and processing operation from the 1920s through 1990. While in operation, Libby was the world's largest source of vermiculite. Libby vermiculite is contaminated with a highly toxic amphibole asbestos. This has resulted in substantial asbestos-related illness and death not only in vermiculite workers, but family members, and residents with no occupational exposure. SUF1.

In 1999, reports of pervasive asbestos-related disease in Libby prompted a concerted response by the federal government, a large component of which was community-based screening by the Agency for Toxic Substances and Disease Registry (ATSDR). SUF2. In 2010, Congress included language in the Affordable Care Act (ACA, Public Law 111-148) to continue to make screening available to persons with potential exposure to vermiculite while they resided in the Libby area. SUF3.

Pursuant to the Affordable Care Act, 42 USC §1881A(e)(2)(B)(i)(I)-(II).the diagnosis for "Asbestosis, pleural thickening, or pleural plaques" is "established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or (II) such other diagnostic standards as the Secretary specifies, except that this clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses." SUF4. Physicians at CARD are "qualified physicians" for purposes of the ACA. SUF5.

In 2011, ATSDR awarded a four-year grant to CARD to conduct screening activities under the ACA. SUF6-7. For purposes of the ATSDR grant, a screened individual was deemed positive if interpretation of computed tomography (CT) of the chest by qualified physicians (a physician with board certification in radiology

or pulmonary medicine or an interpretation provided by the CARD Clinic, for patients in the Libby area) established that asbestosis, pleural thickening, or pleural plaques were present, SUF9, or if interpretation of a plain x-ray of the chest by a B-Reader establishes that asbestosis, pleural thickening, or pleural plaques are present. SUF11. Persons with positive screening results may be eligible for Medicare benefits. SUF12.

ATSDR awarded two subsequent grants to CARD, essentially extensions of 2011 grant, for the periods 2015-19 and 2019-24. SUF13-15. As part of compliance with the terms of the grants, CARD has submitted annual reports and budget justifications to ATSDR; submitted quarterly reports to ATSDR; and CARD staff has worked closely with ATSDR to ensure compliance with the terms of the grants. SUF16-18. Almost all of CARD's funding comes from the ATSDR screening grants. SUF39.

Screening initially consists of a one-page application and proof of presence to determine if a person has sufficient exposure history and latency to qualify for screening under the ATSDR grant, an interview, exposure history and medical history questionnaires, spirometer test, posterior-anterior chest x-ray, and visit with a CARD medical provider. SUF21. If determined appropriate by CARD medical providers, the patient is scheduled for a CT scan, which is then read by a radiologist, typically located where the CT scan is performed. SUF22-23.

CARD physicians apply American Thoracic Society (ATS) guidelines when making positive asbestos-related disease (ARD) diagnoses. Per the guidelines, in addition to structural radiographic abnormalities, clinically positive determinations of ARD are made by CARD's medical providers based on individual evaluation of sufficient exposure, adequate latency, physical evaluation including symptoms assessment and ruling out other plausible causes of clinical and radiographic abnormalities. SUF24.

If CARD physicians determine that a patient has an asbestos-related disease and the patient requests it, CARD staff fill out an Environmental Health Hazards (EHH) checklist for signature by a CARD physician. CARD forwards the EHH checklist to the Social Security Administration. Patients who are diagnosed with as asbestos-related disease by CARD physicians as noted on the EHH checklist are eligible for Medicare benefits under the Affordable Care Act. After passage of the Affordable Care Act in 2010, the Social Security Administration devised the EHH checklist that CARD uses. The EHH checklist SSA sent to CARD in 2010 is the version still in use at CARD today. SUF25-27. After the Affordable Care Act became law, and continuing today, CARD staff has worked closely with the SSA to implement the new provisions of the Affordable Care Act. Notably, SSA presented CARD with an award for its "Outstanding Partnership with SSA in Medicare Outreach to Individuals with Asbestos Related Disease." SUF37-38.

As part of the ATSDR grants, CARD established a panel of B-Readers to review plain chest x-rays and CT scans of screening participants, and CARD staff send radiographic images of patients to the outside readers for interpretation. The outside readers fill out a form for each radiograph or CT scan they interpret and send the forms back to CARD. SUF29. If an outside reader interprets an asbestos-related condition or a qualifying condition on a radiographic image, and the patient requests it, CARD staff fill out an EHH checklist and designate that the asbestos-related condition or qualifying condition was determined by an outside reader. This is a designation not required on the EHH checklist, but used for recordkeeping and grant reporting by CARD. The EHH checklist is then signed by a CARD physician. CARD forwards the EHH checklist to the Social Security Administration. SUF30. Outside reader interpretations do not play a role in the diagnostic decisions of CARD physicians. SUF33.

In 2015, in response to complaints that CARD providers were "over diagnosing" asbestos related diseases, the Department of Health and Human Services Office of Inspector General launched an investigation of CARD. After the investigation the government did not pursue claims against CARD. SUF40-41.

In 2019, the Department of Health and Human Services Office of Inspector General requested the SSA OIG to investigate CARD and/or Dr. Brad Black. On October 15, 2019, the HHS OIG served a subpoena duces tecum on CARD seeking

CARD's patient and financial records, to which CARD fully responded. The SSA OIG released its report on December 5, 2019. The report noted that Dr. Black's CT interpretations "frequently differed" from other providers, and that Dr. Black's interpretations frequently found pleural-based changes, while other providers did not. After the HHS OIG investigation the government did not pursue claims against CARD. SUF42-45.

III. Discussion

In light of the requisite summary judgment standards, CARD examines BNSF's allegations, demonstrating that CARD is entitled to judgment as a matter of law.

A. BNSF's allegations

In BNSF's Third Amended Complaint, Dkt#66, BNSF itemizes CARD's alleged fraudulent acts in 16 Tables, see Dkt#66-1, which are addressed seriatim below.

Table 1 (Dkt#66 ¶261)

The Environmental Health Hazards (EHH) checklists for the individuals in Table 1, one for Dr. Brad Black and one other patient, were signed by Michelle Boltz, FNP, not by a physician. Dr. Black testified that the other patient's EHH was signed by Michelle Boltz at his direction. Ex335 148:10-20. Regarding his own EHH, Dr. Black testified that he asked FNP Boltz to look at his scan to get a

second opinion because he did not want to be the only one to look at his own scan. Ex335 151:9-152:25. The ATSDR Funding Opportunity Announcements state that positive determinations are made by a CT "interpretation provided by the Center for Asbestos-Related Diseases (CARD) Clinic, for patients in the Libby area." Ex301 at 5; Ex302 at 7; Ex302 at 7. FNP Boltz, though not a physician, signed the two EHH forms at issue in Table 1 at the direction of Dr. Black. *See* Ex333 ¶20.

Table 2 (Dkt#66 ¶262)
Table 5 (Dkt#66 ¶¶265)
Table 6 (Dkt#66 ¶266)
Table 7 (Dkt#66 ¶267)

CARD providers diagnosed the eight of the ten individuals in Table 2 with an asbestos-related disease (ARD). CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. The ten individuals in Table 2 are current or former CARD staff or board or CARD staff or board relatives. Outside readers did not make ARD determinations for these individuals. Individual #6 and Individual #8 have not been diagnosed with an ARD; their outside reads were negative, and neither has an EHH checklist. *See* Ex333 ¶20.

CARD providers diagnosed the 23 individuals in Table 5 with an asbestos-related disease. CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. Outside readers made

positive determinations for individuals #5,17,20,21 & 22. Outside readers did not make ARD determinations for the remaining individuals. *See* Ex333 ¶20.

CARD providers diagnosed the 27 individuals in Table 6 with an asbestos-related disease. CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. Of the 27 patients, 6 had radiology reports with finding identified as maybe asbestos related disease: # 5,6, 7,8,9 & 26. Another four had finding on radiology reports that are typical of asbestos related disease due to Libby amphibole exposure but made no mention of ARD: # 1,10,20 & 21. CARD providers prescribed opioid medications at least once for each of the 27 individuals in Table 6. *See* Ex333 ¶20.

CARD providers diagnosed the individuals in Table 7 with an ARD. All 333 patients were diagnosed by CARD and not by B-read alone. Of these 333 patients, 55 had radiology reports with findings reported as possibly due to ARD (#7,11,13, 15,20,23,24,29,33,40,41,42,47,65,70,75,82,84,87,92,97,102,103,108,113,126,127, 128,132,139,142,167,172,174,185,189,206,216,226,228,229,232,240,249,250, 253,256,283,284289, 291,304,310,311,322,328), while another 51 had findings on radiology reports that are typical of or at least suspicious for ARD due to Libby amphibole asbestos, but there was no mention of ARD (#2,8,9,28,31,36,43,46,48, 49,57,60,78,83,91,94,95,96,99,101,105,109,122,124,136,137,140,141,146,150, 181,188,194,215,247,254,259,267,270,272,285,290,316,318,324,326,327). CARD

staff filled out and signed an EHH checklist for each of these individuals who requested it and forwarded the checklist to SSA. No EHH was filed for 35 of the 333 individuals (#23,27,31,32,50,56,57,58,63,69,78,84,85,104,107,114,120,121, 124,149,157,161,170,236,252,255,268,277,287,297,302,321,331,332). *See* Ex333 ¶20.

BNSF's fraud allegation for Tables 2, 5, 6, and 7 appears to be that CARD physicians diagnosed these individuals with an ARD and filled out EHH checklists for these individuals, even though outside readers did not make ARD determinations for these individuals. As noted above, while most of the individuals in Tables 2, 5, 6, and 7 did not have positive outside reads, a limited number did have positive outside reads.

The express terms of 42 USC §1881A(e)(2)(B)(i)(I) provide that the diagnosis for "Asbestosis, pleural thickening, or pleural plaques" is "established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary." Medical providers at CARD have been determined to be "qualified physicians." *See* Ex304; Ex301 at 5; Ex302 at 7; Ex302 at 7. Thus CARD physicians have been empowered by statute and by ATSDR to diagnose these asbestos-related diseases. The outside radiographic scan

readers' determinations do not play a role in the diagnostic process for CARD physicians. Ex335 32:7-14; 27:14-19; Dkt#42 ¶67.

If CARD diagnoses individuals with an ARD, and the patients request it, CARD staff fill out an EHH checklist, *see* Ex332, and forward the EHH checklist to the Social Security Administration. Patients who are diagnosed with an ARD by CARD physicians as noted on the EHH checklist are eligible for Medicare benefits under the Affordable Care Act. Ex333 ¶7; Ex304 at ¶8; Ex1 at 2.

BNSF's allegations of fraud appear to be that CARD diagnosed asbestos-related diseases for the individuals in Tables 2, 5, 6, and 7, but outside readers did not make determinations of asbestos-related diseases. BNSF appears to argue either that it was fraudulent that CARD did not rely on the outside reads to make diagnoses or that it was fraudulent that CARD's diagnoses did not match the outside reads. As discussed below, these medical decisions are not the bases of fraud.

Table 3 (Dkt#66 ¶263)

CARD medical providers did not initially diagnose the 112 individuals in Table 3 with an ARD, but outside readers made determinations of ARD or qualifying conditions when the outside readers reviewed the individuals' radiology images. Because outside readers made the determinations, CARD staff filled out EHH checklists for the individuals if the patients requested it, denoted that an

outside reader had made the determinations, CARD medical providers signed the EHH checklist, and CARD forwarded the checklist to the SSA. CARD then informed the individuals that outside readers had made a determination of an asbestos-related disease. *See, e.g.,* Ex2.; Ex333 ¶¶10-12. Individuals #7,9,33,39, 44,45,47,49,60,61,64,69,70,91,92,98,102,104,105 & 108 of the Dr. Black cohort in Table 3 were initially not diagnosed with an asbestos related disease, but then were diagnosed by CARD later in a subsequent clinic visit. Individual #2 in the Dr. Morrissette cohort was originally diagnosed in 2002, and returned twenty years later and requested an EHH checklist. *See* Ex333 ¶20.

Converse to the situation with Tables 2, 5, 6, and 7, BNSF's fraud allegation appears to be that even though CARD physicians did not initially diagnose these individuals with an ARD, CARD filled out EHH checklists for these individuals regardless because outside readers made ARD determinations for these individuals – even though CARD did not diagnose these individuals with an ARD.

The express terms of 42 USC §1881A(e)(2)(B)(i)(I) provide that the diagnosis for "Asbestosis, pleural thickening, or pleural plaques" is "established by (I) interpretation by a 'B Reader' qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary." The outside readers who review the scans for CARD are "qualified physicians." *See* Ex304; Ex301 at 5; Ex302 at 7;

Ex302 at 7. Thus the outside readers have been empowered by statute and by ATSDR to make determinations about asbestos-related diseases.

As with Tables 2, 5, 6, and 7, BNSF appears to argue either that it was fraudulent that CARD did not rely on the outside reads to make diagnoses or that it was fraudulent that CARD's diagnoses did not match the outside reads. Again, as discussed below, these medical decisions are not the bases of fraud.

Table 4 (Dkt#66 ¶264)

CARD diagnosed six of the seven individuals in Table 4 with an ARD. CARD staff filled out and signed an EHH checklist for each of these individuals who requested it, and forwarded the checklist to SSA. Outside readers made positive determinations for Individuals #1 & #3 first, then #1 & #3 were later diagnosed in clinic by CARD. Individuals #2,4,5 & 7 were diagnosed in clinic by CARD but had negative outside reads, while Individual #6 was not diagnosed in clinic but had a positive outside read. *See* Ex333 ¶20.

The arguments for the diagnoses and outside reads applicable to the previous tables apply to the individuals in Table 4 as well.

Table 8 (Dkt#66 ¶268)

CARD diagnosed the nine individuals in Table 8 with an ARD. CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. Two of the nine (#5 & 8) have asbestos-related abnormalities

identified by outside readers. Three others (#4,6 & 9) had findings on radiology reports that are typical of or at least suspicious for ARD due to Libby amphibole asbestos but there was no mention of ARD. For the other four, radiologists did not make asbestos-related disease determinations for these individuals. Four of the nine individuals in Table 8 made disability claims that were supported by CARD medical providers (#1,4,5 & 6), for the others CARD provided medical records but not a letter of support.

BNSF's fraud allegation here appears to be that CARD's support of the disability determinations was fraudulent because outside readers did not make ARD determinations for these individuals. To the extent that the fraud allegations pertain to the diagnoses and outside reads for these individuals, the arguments for the diagnoses and outside reads applicable to the previous tables apply to the individuals in Table 8 as well.

Table 9 (Dkt#66 ¶268)
Table 10 (Dkt#66 ¶268)
Table 12 (Dkt#66 ¶268)

CARD diagnosed the 22 of 26 individuals in Table 9 (but did not diagnose #6,9,12 or 15) the last seven individuals in Table 10, and the seven individuals in Table 12 with an ARD. CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. 24 of the 26 in table 9 had outside reads positive for an asbestos-related abnormalities and 8 received

Medicare based on their age prior to EHH submission (#3,6,11,13,14,16,18 & 22). Outside readers did not make ARD determinations for the remaining individuals but three from table 12 had findings on radiology reports that are typical of ARD due to Libby amphibole asbestos but there was no mention of ARD (#1,4 & 6.) SSA approved all of these individuals for Medicare benefits. When these individuals later came to CARD for office visits after these individuals had been granted Medicare benefits, CARD billed Medicare for the office visits.

CARD diagnosed the first 16 individuals in Table 10 with an ARD. CARD staff filled out and signed an EHH checklist for each of these individuals and forwarded the checklist to SSA. Outside readers did not make ARD determinations for these individuals but three (#5,7 & 8) had findings on radiology reports that are typical of ARD due to Libby amphibole asbestos but no mention of ARD was made. CARD providers prescribed opioid medications at least once for each of the first 16 individuals in Table 10. SSA approved these individuals for Medicare benefits but 2 received Medicare prior to EHH designation (#6 & 15). When these individuals later came to CARD for office visits after these individuals had been granted Medicare benefits, CARD billed Medicare for the office visits. *See* Ex333 ¶17.

BNSF appears to argue either that it was fraudulent that CARD did not rely on the outside reads to make diagnoses or that it was fraudulent that CARD's

diagnoses did not match the outside reads, and further, that CARD billed Medicare for services for these individuals when the basis for SSA providing Medicare benefits to these individuals was CARD's diagnosis of an ARD, even though some were age-qualified for Medicare prior to the diagnoses.

Table 11 (Dkt#66 ¶268)

Similar to Table 3, above, CARD medical providers did not diagnose the individual in Table 11 with an ARD upon initial screening, but an outside reader made a determination of ARD when the outside reader reviewed the individual's scan. BNSF appears to argue either that it was fraudulent that CARD did not rely on the outside reads to make a diagnosis or that it was fraudulent that CARD's diagnosis did not match the outside read, and further, that CARD billed Medicare for services for this individual when the basis for SSA providing Medicare benefits to this individual was the outside read when CARD had not made a diagnosis of an ARD.

Table 13 (Dkt#66 ¶268)

Of the 17 individuals in Table 13, three (#6,7,13) have never been diagnosed by CARD. The table appears to be payments made to pharmacies that billed Medicare for 17 individuals who had been prescribed opioids by CARD providers.

Table 14 (Dkt#66 ¶268)

Table 14 has no entries.

Table 15 (Dkt#66 ¶268)

BNSF alleges that CARD made four false statements in CARD's Final Report to ATSDR in 2015. Ex344. CARD addresses each allegation in turn:

1. "CARD's Diagnosis rate for ARD is Consistent with Radiologist's Read Rate for ARD: The 'dissention[sic]' between the CARD diagnosis rate and the Outside Reader diagnosis rate is 6% - or '47% v. 41%.' This dissension rate is closer to 70% according to CARD staff."

Here BNSF is referring to Ex344 at 19, "CARD's diagnosis rate is 47% versus a 41% diagnosis rate by outside readers . . . ." The percentage of positive reads by outside readers is based upon the number of CT scans they review, but not every screening participant gets a CT scan. Whereas the percentage of CARD's diagnoses is based upon the number of patients screened, not just the number of CT scans. This is explained elsewhere in the report. *See* Ex344 at 1 (Table 1), 4 (Table 7). *See also* Ex334 153:4-159:23.

2. "CARD uses its Outside Radiology Reads to ensure Accuracy: 'Outside Radiology Reads are conducted by five b-readers, including three radiologists who make up "the outside reader panel that would over-read every image taken through the screening grant.'"

Here BNSF is referring to Ex344 at 4, "**Outside Radiology Reads:** Five B-readers, which included three radiologists, made up the outside reader panel that would over-read every image taken through the screening grant." As part of the ATSDR grants, CARD established a panel of B-Readers to review plain chest x-rays and CT scans of screening participants. The members of the B-Reader panel

were chosen in conjunction with and approved by ATSDR. Ex316 at 7-8. Every image taken through the grant is sent to be read by a member of the panel and those results are detailed in each quarterly report.

3. "CARD's peer-review program is used to ensure accuracy of reads and 'quality control.' CARD claims it does not track its error rate or update its 'diagnostic dissension' rate; CARD does not use B-reads for any diagnostic purpose and does not use Peer-review data for any purpose."

The statements alleged by BNSF to be false in #3 do not appear in Ex344, but rather appear to be BNSF's allegations about CARD that are responses to Ex344. The outside reader panel is used for quality control for the screening program by allowing comparisons between CARD's interpretations and the outside reader interpretations, as well as the comparisons between the different outside readers. *See, e.g.,* Ex302 at 8 ("this review will have no influence on already established status of patient benefits under the program, but will serve solely to bring consistency to the screening program"). It is true that outside reader interpretations do not play a role in the diagnostic decisions of CARD physicians. Dkt#42 ¶67. In 2021 as part of the $1M in supplemental funding, work was approved to validate imaging software in order to help address the disagreement between readers including CARD's reads.

4. "CARD suggests that it follows the Affordable Care Act rule that a diagnosis of asbestos related disease is required to obtain Medicare benefits: 'Traditional Medicare is available for individuals diagnosed with ARD as a result of Libby asbestos exposure regardless of age or disability status. This is facilitated by placing an EHH (Environmental health Hazard) designation on an individual's

Medicare status if they are diagnosed with Libby ARD.' … 'Also of note, CARD is able to report on the number of EHH designated individuals under and over the age of 65 because we verify their diagnoses, but we cannot guarantee that these individuals completed all of the other enrollment steps with Medicare.' Multiple CARD witnesses testify that CARD knowingly submits patients to the Social Security Administration for EHH Medicare benefits without any diagnosis of asbestos related disease."

Here BNSF is referring to Ex344 at 7 and quotes two statements in the report. BNSF appears to argue that these are false statements because some of the EHH checklists forwarded to SSA do not have CARD diagnoses, but rather positive outside reads. As explained above, the Affordable Care Act provides for both individuals diagnosed by CARD and individuals determined positive by outside readers to have EHH checklists sent to SSA to enrollment in Medicare benefits. *See, e.g.,* Ex304. These statements in the report are not false.

Table 16 (Dkt#66 ¶268)

BNSF alleges in Table 16 that CARD falsely claimed $5,500 "for CT Scans at CARD," when there has never been a CT scanner at CARD.

It is true that CARD has never had a CT scanner on site. The document BNSF refers to is a subaward for a previous research grant that had nothing to do with CARD's Screening grant. The term "CT scans at CARD" was used to differentiate between a cohort of CT scans at Mount Sinai and a cohort of CT scans at CARD because the study was looking at two separate cohorts of asbestos-

exposed populations. The statement does not refer to CT scans actually taken at CARD; no CT scans have ever been taken at CARD.

B. False Claims Act

Claims under the False Claims Act (FCA) require a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Gilead*, 862 F.3d at 902. The false claim or statement must be the "*sine qua non* of receipt of state funding," *Id.* (citation omitted).

"The False Claims Act is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Services, Inc., v. United States ex rel. Escobar,* 579 U.S 176, 194 (2016) (internal citations omitted). Moreover, materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* "If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id*. at 195.

C. Bases to BNSF's FCA Claims

The bases of BNSF's argument appear to be three-fold: First, that CARD has made false statements to the ATSDR to induce ATSDR to give CARD federal funds in the form of grant payments. Second, that CARD's medical providers' diagnoses of ARD when outside readers disagree with those diagnoses is essentially a type of false certification claim under the FCA. Third, that the converse – when an outside reader determines an asbestos-related disease when CARD does not diagnose an asbestos-related disease – is also a type of false certification under the FCA. Then, when CARD submits requests for payment to Medicare for care CARD provides to its ARD patients who are on Medicare because of an EHH checklist provided to the SSA by CARD, BNSF appears to allege that CARD is making a fraudulent claim for payment.

However, vitiating the bases to BNSF's claims are the ACA provisions which provide that regardless of whether the diagnosis of an ARD is made by CARD or whether the determination is made by an outside reader, either results in eligibility for Medicare benefits. Ex305; 42 USC §1881A(e)(2)(B)(i)(I).

Moreover, claims under the FCA require a showing of "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Gilead,* 862 F.3d at 902. CARD examines each element below.

(1) False statement

A physician's medical opinion can be considered "false" within the meaning of the FCA under some circumstances, such as where the opinion is not honestly held by the doctor. *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*, 953 F.3d 1108, 1117-18 (9th Cir. 2020). Notably, "The FCA requires the knowing presentation of what is known to be false and that the phrase known to be false does not mean 'scientifically untrue,' it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors." *Id.* (citations omitted).

Here, the CARD medical providers' diagnoses for asbestos-related diseases are based on the American Thoracic Society 2004 Guidelines. Ex335 at 17:14-18:23. Further, CARD providers' diagnoses of patients with asbestos-related diseases are based on over two decades of familiarity with the presentation of Libby amphibole disease in patients. *See* SUF47. Simply stated, the diagnostic opinions of the CARD providers are "honestly held," therefore cannot be false statements under the FCA.

Far from demonstrating fraudulent asbestos-related disease diagnoses by CARD, the facts underlying BNSF's claims instead show no more than the noted discrepancies in clinical judgment between CARD providers and outside readers. The record demonstrates that CARD providers present honestly held opinions

regarding the presence or absence of asbestos-related disease based on a disease presentation documented in decades of peer-reviewed medical literature, including literature co-authored by CARD providers. SUF47. Several of these peer reviewed studies and publications specifically discuss the radiographic presentation of pleural disease among the Libby cohort and the difficulties presented in uniform classification from a radiographic standpoint. SUF47. Beyond Libby, interreader variability is a recognized phenomenon often leading to differing opinions of the presence, absence, or degree of radiographic findings among different readers reviewing the same image. SUF48. As such, it is not surprising, and certainly not fraudulent, that there is some variability in reads and diagnoses of CARD providers and other readers. *See, e.g., Holzner v. Davita, Inc.,* 2022 WL 726929 at *1 (9th Cir. March 10, 2022)(mere disagreement in clinical judgement is insufficient evidence to establish that medical diagnoses or certifications are false or fraudulent).

Moreover, Congress passed the Affordable Care Act in 2010 with provisions written specifically to enable CARD providers to diagnose asbestos-related diseases to expand Medicare eligibility for people exposed to environmental health hazards in the Libby area. Ex304; Ex305. After the Affordable Care Act became law, CARD staff worked with the SSA to implement the new provisions of the Affordable Care Act, including the EHH checklist, Ex332, and have continued to

work closely with SSA. Ex333 ¶19. Emblematic of this cooperative relationship, SSA presented CARD with an award for its "Outstanding Partnership with SSA in Medicare Outreach to Individuals with Asbestos Related Disease." Ex336. CARD staff repeatedly testified that they were conforming to SSA directions when filling out the EHH checklists for Medicare eligibility. *See, e.g.,* Ex335 70:13-72:24.

Finally, regarding BNSF's allegations of false statements in grant reports to ATSDR, as explained above, the statements are not false.

(2) Scienter

The scienter requirements of the FCA are "rigorous." *Escobar*, 579 U.S. at 192. In *Winter*, the Ninth Circuit considered whether providing false certifications of medical necessity for hospital admissions decisions for Medicare patients were actionable under the FCA. The Ninth Circuit stated that, "Defendants act with the required scienter if they know the treatment was not medically necessary, or act in deliberate ignorance or reckless disregard of whether the treatment was medically necessary." *Winter*, 953 F.3d at 1114. Notably, the Ninth Circuit stated that, "falsity is a necessary, but not sufficient, requirement for FCA liability—after alleging a false statement, a plaintiff must still establish scienter. … a 'scientifically untrue' statement is 'false'—even if it may not be actionable because it was not made with the requisite intent. And an opinion with no basis in fact can be fraudulent if expressed with scienter." *Id*. at 1118.

Here, the diagnostic opinions of the CARD providers here are "honestly held" and soundly based on the decades of extensive medical research and peer reviewed literature on the subject of Libby asbestos-related disease. *See, e.g.,* SUF47. Moreover, CARD's statements in its grant reports are known by CARD to be true. The scienter requirement cannot be met here.

(3) Materiality

Under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 USC §3729(b)(4). The materiality standard is both "rigorous" and "demanding" because the FCA is not "an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S at 192, 194 (citations omitted). "Under any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation," meaning the government. *Id*. at 193 (citations omitted).

In *United States ex rel. Rose v. Stephens Institute*, the Ninth Circuit explained three materiality scenarios from *Escobar*:

> First, 'proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.' Second, the Court explained that, 'if the Government pays a particular claim in full despite its *actual knowledge* that certain requirements were violated, that is

> very strong evidence that those requirements are not material.' Third, "if the Government regularly pays a particular type of claim in full despite *actual knowledge* that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.' The Court further noted that materiality 'cannot be found where noncompliance is minor or insubstantial.'

United States ex rel. Rose v. Stephens Institute, 909 F.3d 1012, 1019 (9th Cir. 2018) (internal citations omitted). For a false statement to be material, the statutory violations must be "so central" to the claims that the government "would not have paid these claims had it known of these violations." *Winter*, 953 F.3d at 1121 (*quoting Escobar*, 579 U.S at 196).

The provisions of the Affordable Care Act were crafted to ensure that CARD providers would be considered qualified to diagnose asbestos related diseases. Ex304. After passage of the Affordable Care Act, the ATSDR sent out a Funding Opportunity Notice that specifically included provisions acknowledging that CARD providers are considered qualified to diagnose asbestos related diseases. *See* Ex301 at 5. Throughout the years of all three ATSDR grants to CARD, CARD has submitted quarterly reports, annual reports, and budget justifications to ATSDR. *See, e.g.,* Ex310-Ex331. On each of these reports, CARD staff has worked closely with ATSDR staff. Ex333 ¶4. ATSDR is aware of CARD providers' diagnostic rates and rates of dissension with outside readers, yet ATSDR has continued funding the grants to CARD. Ex333 ¶¶13-15. Moreover, even after HHS OIG conducted an investigation of CARD in 2019 in response to

this lawsuit, and even after BNSF has chosen to prosecute this case after the government chose not to intervene, in 2021 ATSDR awarded CARD a $1 million supplemental grant to expand the screening program. Ex341.

Here materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation, here ATSDR. Whatever allegations that BNSF attempts to posit here, it is clear from the actions of ATSDR continuing to fund CARD, and even providing CARD with supplemental funding during the pendency of BNSF's litigation, that any alleged false statements are not material, and certainly cannot withstand the "rigorous" and "demanding" materiality requirements demanded by the FCA.

Further, the actions of SSA indicate that it is certainly aware of how CARD staff fill out EHH checklists, since SSA created the EHH checklists and provided CARD with the checklists after the Affordable Care Act was enacted. Ex332. Moreover, CARD staff continue to work closely with SSA with the EHH checklists. Ex333 ¶19. As noted above SSA presented CARD with an award for its "partnership" in providing Medicare benefits to individuals with asbestos-related diseases. Ex336.

(4) Government payments

BNSF's allegations appear to be that ATSDR paid grant funds to CARD based on CARD's false statements; that Medicare paid CARD for treatment CARD

provided to Medicare patients who CARD had diagnosed with an asbestos-related disease – or outside readers had determined had an asbestos-related disease – based on EHH checklists with false statements CARD submitted to SSA; that secondary Medicare insurers paid CARD for these patients; and that Medicare paid for opioid prescriptions for these patients.

As discussed above, SSA provided the EHH checklist to CARD and SSA has been aware of how CARD staff fill out the EHH checklist. Funds have never been withheld for Medicare patients treated at CARD. Ex333 ¶16. Notably, ATSDR grant funding has never been withheld by ATSDR. Ex333 ¶15.

D. Statute of Limitations

As set forth above, required elements of an FCA claim are not met here, which failure is determinative. Moreover, under 31 USC §3731(b)(1) & (2), the statute of limitations for FCA claims is six years after the date of the alleged violation of §3729, or three years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, whichever occurs last. The three-year statute applies even in cases in which the government declines to intervene. *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S.Ct. 1507 (2019). The three-year statute of limitations applies here.

In 2015 complaints were filed with the Office of Inspector General of the Department of Health and Human Services, alleging that Dr. Black was "over diagnosing patients with asbestos." Ex337-Ex340. Accordingly, it appears on the record before the Court that BNSF's claims are time-barred. Alternatively, at the least many of BNSF's specific allegations of false statements are time-barred because the "official of the United States charged with responsibility to act in the circumstances" the HHS OIG, was aware of the "facts material to the right of action" at least as of the 2015 investigation, yet did not bring any claims. Thus, BNSF would have had to bring its claims under the FCA by late 2018 or January of 2019 at the latest. *See* Ex337-Ex340.

Finally, in the alternative, BNSF's specific allegations are time-barred under §3731(b)(1).

IV. Conclusion

This Court should grant CARD's Motion for Summary Judgment. First, vitiating the bases to BNSF's claims are the ACA provisions which provide that regardless of whether the diagnosis of an ARD is made by CARD or whether the determination is made by an outside reader, either results in eligibility for Medicare benefits. Ex305; 42 USC §1881A(e)(2)(B)(i)(I). Moreover, the scienter and materiality elements of a False Claims Act cannot be met here: Unarguably, the CARD providers believe that their diagnoses are correct, and they are

empowered to make these diagnoses by statutory provisions in the Affordable Care Act. Significantly, ATSDR has continued to fund CARD throughout this lawsuit and has even awarded CARD a supplemental grant of $1 million to expand the screening program. Finally, BNSF's allegations are time-barred because the Department of Health and Human Services OIG knew or should have known of these same allegations due to a complaint in 2015.

Summary judgment for CARD is appropriate.

DATED this 15th day of April 2022.

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief is 6464 words, excluding the caption, table of contents, table of authorities, index of exhibits, signature blocks, and certificate of compliance. Pursuant to Local Rule 7.1, a table of contents, table of authorities, and index of exhibits are included in this brief.

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